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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/908,943	07/19/2001	Riqiang Yan	29915/00281A.US	1034

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[REDACTED] EXAMINER

PATTERSON, CHARLES L JR

[REDACTED] ART UNIT [REDACTED] PAPER NUMBER

1652

DATE MAILED: 09/19/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/908,943	YAN ET AL.
	Examiner Charles L. Patterson, Jr.	Art Unit 1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on _____.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-82 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) _____ is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) 1-82 are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

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There are handwritten interlineations changing claim 58 to 64 and 67 and 68 to 66 and 67. These interlineations are not initialed and therefore they need to be corrected by amendment. The claim number they have been changed to are referred to in the instant restriction requirement as they would have been changed under 37 CFR 1.126 if no interlineations had been made.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

1. Claims 1-20, 28-35, drawn to a peptide of SEQ ID NO: 5, classified in class 530, subclass 327.
2. Claims 1-20, 28-35, drawn to a peptide of SEQ ID NO: 6, classified in class 530, subclass 326.
3. Claims 1-20, 28-35, drawn to a peptide of SEQ ID NO: 7, classified in class 530, subclass 327.
4. Claims 1-20, 28-35, drawn to a peptide of SEQ ID NO: 8, classified in class 530, subclass 328.
5. Claims 1-20, 28-35, drawn to a peptide of SEQ ID NO: 9, classified in class 530, subclass 328.
6. Claims 1-20, 28-35, drawn to a peptide of SEQ ID NO: 10, classified in class 530, subclass 328.
7. Claims 1-20, 28-35, drawn to a peptide of SEQ ID NO: 11, classified in class 530, subclass 328.
8. Claims 1-20, 28-35, drawn to a peptide of SEQ ID NO: 12, classified in class 530, subclass 328.
9. Claims 1-20, 28-35, drawn to a peptide of SEQ ID NO: 13, classified in class 530, subclass 328.

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10. Claims 1-20, 28-35, drawn to a peptide of SEQ ID NO: 14, classified in class 530, subclass 328.
11. Claims 1-20, 28-35, drawn to a peptide of SEQ ID NO: 15, classified in class 530, subclass 328.
12. Claims 1-20, 28-35, drawn to a peptide of SEQ ID NO: 16, classified in class 530, subclass 328.
13. Claims 1-20, 28-35, drawn to a peptide of SEQ ID NO: 17, classified in class 530, subclass 328.
14. Claims 1-20, 28-35, drawn to a peptide of SEQ ID NO: 18, classified in class 530, subclass 328.
15. Claims 1-20, 28-35, drawn to a peptide of SEQ ID NO: 120, classified in class 530, subclass 328.
16. Claims 1-20, 28-35, drawn to a peptide of SEQ ID NO: 133, classified in class 530, subclass 328.
17. Claims 1-20, 28-35, drawn to a peptide of SEQ ID NO: 134, classified in class 530, subclass 328.
18. Claims 1-20, 28-35, drawn to a peptide of SEQ ID NO: 135, classified in class 530, subclass 328.
19. Claims 1-20, 28-35, drawn to a peptide of SEQ ID NO: 136, classified in class 530, subclass 328.
20. Claims 1-20, 28-35, drawn to a peptide of SEQ ID NO: 137, classified in class 530, subclass 328.
21. Claims 1-20, 28-35, drawn to a peptide of SEQ ID NO: 138, classified in class 530, subclass 328.
22. Claims 1-20, 28-35, drawn to a peptide of SEQ ID NO: 141, classified in class 530, subclass 328.

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23. Claims 1-20, 28-35, drawn to a peptide of SEQ ID NO: 143, classified in class 530, subclass 328.
24. Claims 1-20, 28-35, drawn to a peptide of SEQ ID NO: 144, classified in class 530, subclass 328.
25. Claims 1-20, 28-35, drawn to a peptide of SEQ ID NO: 145, classified in class 530, subclass 324.
26. Claims 1-20, 28-35, drawn to a peptide of SEQ ID NO: 147, classified in class 530, subclass 326.
27. Claims 1-20, 28-35, drawn to a peptide of SEQ ID NO: 148, classified in class 530, subclass 328.
28. Claims 1-20, 28-35, drawn to a peptide of SEQ ID NO: 149, classified in class 530, subclass 328.
29. Claims 1-20, 28-35, drawn to a peptide of SEQ ID NO: 150, classified in class 530, subclass 328.
30. Claims 1-20, 28-35, drawn to a peptide of SEQ ID NO: 151, classified in class 530, subclass 328.
31. Claims 1-20, 28-35, drawn to a peptide of SEQ ID NO: 152, classified in class 530, subclass 328.
32. Claims 1-20, 28-35, drawn to a peptide of SEQ ID NO: 153, classified in class 530, subclass 328.
33. Claims 1-20, 28-35, drawn to a peptide of SEQ ID NO: 154, classified in class 530, subclass 327.
34. Claims 1-20, 28-35, drawn to a peptide of SEQ ID NO: 155, classified in class 530, subclass 326.
35. Claims 1-20, 28-35, drawn to a peptide of SEQ ID NO: 156, classified in class 530, subclass 325.

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36. Claims 1-20, 28-35, drawn to a peptide of SEQ ID NO: 157, classified in class 530, subclass 324.
37. Claims 1-20, 28-35, drawn to a peptide of SEQ ID NO: 158, classified in class 530, subclass 327.
38. Claims 1-20, 28-35, drawn to a peptide of SEQ ID NO: 159, classified in class 530, subclass 326.
39. Claims 1-20, 28-35, drawn to a peptide of SEQ ID NO: 160, classified in class 530, subclass 326.
40. Claims 1-20, 28-35, drawn to a peptide of SEQ ID NO: 161, classified in class 530, subclass 324.
41. Claims 1-20, 28-35, drawn to a peptide of SEQ ID NO: 162, classified in class 530, subclass 327.
42. Claims 1-20, 28-35, drawn to a peptide of SEQ ID NO: 163, classified in class 530, subclass 326.
43. Claims 1-20, 28-35, drawn to a peptide of SEQ ID NO: 164, classified in class 530, subclass 326.
44. Claims 1-20, 28-35, drawn to a peptide of SEQ ID NO: 165, classified in class 530, subclass 324.
45. Claims 1-20, 28-35, drawn to a peptide of SEQ ID NO: 166, classified in class 530, subclass 327.
46. Claims 1-20, 28-35, drawn to a peptide of SEQ ID NO: 167, classified in class 530, subclass 326.
47. Claims 1-20, 28-35, drawn to a peptide of SEQ ID NO: 168, classified in class 530, subclass 326.
48. Claims 1-20, 28-35, drawn to a peptide of SEQ ID NO: 169, classified in class 530, subclass 324.

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49. Claims 1-20, 28-35, drawn to a peptide of SEQ ID NO: 190, classified in class 530, subclass 327.
50. Claims 1-20, 28-35, drawn to a peptide of SEQ ID NO: 191, classified in class 530, subclass 326.
51. Claims 1-20, 28-35, drawn to a peptide of SEQ ID NO: 192, classified in class 530, subclass 326.
52. Claims 1-20, 28-35, drawn to a peptide of SEQ ID NO: 193, classified in class 530, subclass 326.
53. Claims 21-27, drawn to a peptide wherein P₂ is N, classified in class 530, subclass 330.
54. Claims 21-27, drawn to a peptide wherein P₂ is S, classified in class 530, subclass 330.
55. Claims 21-27, drawn to a peptide wherein P₂ is D, classified in class 530, subclass 330.
56. Claims 21-27, drawn to a peptide wherein P₁ is Y, classified in class 530, subclass 330.
57. Claims 21-27, drawn to a peptide wherein P₁ is L, classified in class 530, subclass 330.
58. Claims 21-27, drawn to a peptide wherein P₁ is Nle, classified in class 530, subclass 330.
59. Claims 21-27, drawn to a peptide wherein P_{1'} is E, classified in class 530, subclass 330.
60. Claims 21-27, drawn to a peptide wherein P_{1'} is A, classified in class 530, subclass 330.
61. Claims 21-27, drawn to a peptide wherein P_{1'} is D, classified in class 530, subclass 330.

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62. Claims 21-27, drawn to a peptide wherein P_{2'} is A, classified in class 530, subclass 330.

63. Claims 21-27, drawn to a peptide wherein P_{2'} is V, classified in class 530, subclass 330.

64-126. Claims 36-42 and 52-54, drawn to a polynucleotide that encodes the polypeptide of claims 1-35, a vector, a host cell and method of producing a substrate for a β -secretase assay, classified in class 435, subclass 320.1 and 252.3 and class 536, subclass 232.1. The groups 64-126 correspond to groups 1-63.

127-189. Claims 43-50, drawn to a method for assaying for modulators of β -secretase activity, a method of inhibiting β -secretase activity *in vivo*, classified in class 435, subclass 23. The groups 127-189 correspond to groups 1-63.

190-252. Claims 51 and 55-57, drawn to a method of inhibiting the β -secretase activity *in vivo* comprising administering a modulator according to claim 50, a pharmaceutical composition comprising a modulator, a method of treating a disease comprising administering the pharmaceutical composition and the use of a modulator to treat Alzheimer's Disease, classified in various classes and subclasses depending upon what the inhibitor is. The groups 190-252 correspond to groups 1-63.

253-315. Claims 58-64, 66-67, drawn to a method for identifying agents that inhibit Asp2 aspartyl protease and a method of identifying agents that modulate Asp2 aspartyl protease, classified in class 435, subclass 219. The groups 252-315 correspond to groups 1-63.

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316-378. Claims 65 and 68-69, drawn to a method of treating Alzheimer's Disease comprising using an inhibitor of Hu-Asp2, classified in various classes and subclasses depending upon the identity of the inhibitor. The groups 316-378 correspond to groups 1-63.

379-441. Claim 70-72, drawn to a kit for performing a β -secretase assay, classified in class 435, subclass 23. The groups 379-441 correspond to groups 1-63.

442. Claims 73-82, drawn to a peptide, classified in class 530, subclass 328, 327, 326 and 324.

The inventions are distinct, each from the other because:

Groups (1-63) and (64-126) are drawn to completely different chemical compounds that are patentably distinct. Groups (1-63) and 442 are drawn to different structural peptides and as such are patentable distinct from each other. The other groupings correspond to groups 1-63 because they all depend upon groups 1-63.

Inventions (1-63) and (127-189) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process such as in the methods of groups (190-252), (253-315), (316-378) and in the kit or groups (379-441).

Inventions (1-63) and (190-252) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can

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be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process such as in the methods of groups (127-189), (253-315), (316-378) and in the kit or groups (379-441).

Inventions (1-63) and (253-315) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process such as in the methods of groups (127-189), (190-252), (316-378) and in the kit or groups (379-441).

Inventions (1-63) and (316-378) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process such as in the methods of groups (127-189), (190-252), (253-315), and in the kit or groups (379-441).

Inventions (379-441) are drawn to a product (a kit) that is patentably distinct from the products of groups (1-63) and (64-126).

Claim 33 is presumed to be drawn to a polypeptide instead of a fusion protein, since there is no antecedent basis for fusion protein in claims 28-32.

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Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles L. Patterson, Jr., PhD, whose telephone number is 703-308-1834. The examiner can normally be reached on Monday - Friday, 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on 703-308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-0294 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


Charles L. Patterson, Jr.
Primary Examiner
Art Unit 1652

Patterson
September 19, 2002